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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,370	08/05/2003	Daniel K. Tomaschko	S63.1-7132US03	6918
490	7590	09/21/2005	EXAMINER	
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/634,370

Applicant(s)

TOMASCHKO ET AL.

Examiner

Vy Q. Bui

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 42-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-37 and 39-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 38 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/7/2005.

The Applicants traversed the restriction requirement on the grounds that a previous restriction requirement indicated that both allegedly distinct inventions were examinable as a single invention. Group I of the restriction requirement of July 27, 2004, drawn to a method of making a catheter balloon included claims of both alleged inventions I and II.

The Examiner asserts that there are two distinct inventions in the application and it would be a serious burden to examine both distinct and different inventions in an application. However, if the generic claim 33 is allowable, withdrawn dependent claim 38 drawn to a non-elected invention will be rejoined.

### ***Specification***

The amendment filed 1/25/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matters into the disclosure. Section 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: mandrel 200 are disposed inside tubing segment 120 as shown in amended drawings Figs. 3-4 and the amended paragraphs on pages 8 and 9 of the written specification. There are different ways to provide a mandrel to support tubing 120 and the original specification simply did not provide the specific way to support

Art Unit: 3731

tubing 120 as now shown in the amended Figs. 3-4, especially, a mandrel 200 inside tubing segment 120 on blade 122 (Fig. 3).

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matters, which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It is noticed that the claims in the present invention are copied claims of U.S. Pat. 6,488,654-Gonzalez et al., which clearly shows balloon 24 having material of the proximal shaft/waist/skirt or distal shaft/waist/skirt being removed by grinding wheel 46. At the same time, the specification and drawings of the present invention fail to disclose rotating a mandrel so as to rotate a balloon and especially the specification including Figs. 3-4 of this invention does not disclose a balloon but instead disclose a tubing segment 120. A balloon can be inflated at a room temperature, but a balloon preform (parison) is not inflatable at the room temperature.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WANG et al.-5,807,520 in view of WAND et al.-5,525,388.

As to claims 33-37, 39-41, WANG-'520 (col. 1, lines 49-54; col. 2, lines 26-30) discloses that it is well known to reduce balloon waist thickness and balloon cone/tapered portion thickness. WANG does not teach reducing balloon waist thickness and balloon cone/tapered portion thickness by abrading. WAND (Fig. 1-5, col. 2, lines 47-53) discloses a method of thinning a balloon-tapered portion is by machining, abrading the tapered portions of a balloon perform (parison). A material removal process by abrading with a grinding machine to remove the material is well known and it is inherently, the uniformed thicknesses of the waist portions are somewhat different from one another because of the manufacturing tolerance, therefore, Wang inherently has the claim feature (second diameter different from the first diameter). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a grinding machine to thin a balloon material in a process as recited in the claims.

***Response to Arguments***

Applicant's arguments filed 1/25/2005 have been fully considered but they are not persuasive.

As to 35 U.S.C. 112 rejection, it is recognized that in relation to Fig. 4, the original written specification discloses a mandrel may also be used in place or in addition to the die to support

Art Unit: 3731

as needed (page 9, lines 11-12). However, the original written specification and original Fig. 4 have failed to disclose a mandrel disposed inside the segment 120 in a manner as now shown in amended Fig. 4. Further, the original written specification and Fig. 3 simply does not disclose a mandrel to support tubing segment 120 in a manner as now disclosed in the amended written specification and amended Fig. 3, and especially the tubing 120 as a balloon, but rather the original written specification and Fig. 3 disclose a balloon tubing segment 120 as a balloon preform (parison). It is noticed that the claims in the present invention are copied claims of U.S. Pat. 6,488,654-Gonzalez et al., which clearly shows balloon 24 having material of the proximal shaft/waist/skirt or distal shaft/waist/skirt being removed by grinding wheel 46. At the same time, the specification and drawings of the present invention fail to disclose rotating a mandrel so as to rotate a balloon and especially the specification including Figs. 3-4 of this invention does not disclose a balloon but instead disclose a tubing segment/balloon perform (parison) 120. A balloon can be inflated at a room temperature, but a tubing segment or balloon preform (parison) is not inflatable at the room temperature.

As to 35 U.S.C. 103(a) rejection, the Applicants argued that "Both Wang and Wand seek to provide balloons with uniform or constant wall thicknesses (Wang: column 2, lines 25-33; Wand: column 2, lines 46-47). Nowhere do the references, alone or in combination teach or suggest a method of removing material from a balloon wherein removal of said material is to form a shaft section having a first portion with a substantial uniform first diameter and a second portion with a substantially uniform second diameter, different than the first diameter".

However, Wang (col. 2, lines 32-33) discloses "cone and waist walls with reduced, uniform thicknesses" and inherently, the uniformed thicknesses of the waist portions are different from one another due to the manufacturing tolerance, therefore, Wang inherently has the claim feature (second diameter different from the first diameter).

### **Conclusion**

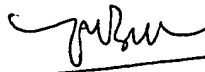
This is a RCE of applicant's earlier application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
09/16/2005  
Vy Q. Bui  
Primary Examiner  
Art Unit 3731